RURAL DEVELOPMENT, AGRICULTURE, AND RELATED AGENCIES APPROPRIATIONS FOR 1989

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDREDTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON RURAL DEVELOPMENT, AGRICULTURE, AND RELATED AGENCIES

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Mr. WATKINS. Thank you, Dr. Young.
Thank you, Mr. Chairman.
Mr. WHITTEN. At this time, we will recess for the vote in the House and come back.
[Recess taken.]
Mr. WHITTEN. The subcommittee will come to order.
Mr. Durbin?
Mr. DURBIN. Thank you, Mr. Chairman.
Dr. Young, thank you for joining us again this year. I have enjoyed working with your agency. You have extraordinary responsibility, and I feel that you and the people who work with you do an extraordinarily good job which is perhaps unheralded. I hope that this hearing today and the reporting of it will help to bring the recognition which you deserve for a job well done.
Dr. YOUNG. Thank you.

TOBACCO

Mr. DURBIN. Your opening remarks, particularly the first page, describes what you have called a "particularly broad mandate" which requires that you educate consumers about the safety of products, and regulate them so that the consumers can participate in protecting their own health.
As an overview of your agency, it would appear that you generally have three options at your disposal: to prohibit certain products, to regulate others, and perhaps in conjunction with either or both of those responsibilities to at least require disclosure so that consumers can make an educated choice.
We have heard during the course of the questions asked of you by my colleagues here a description of many different activities and products, and the role of your agency has been plumbed and explored in terms of regulating those products. I am going to ask you some questions about one particular product that concerns me. It is a product which is consumed by millions of Americans, but its contents are not disclosed. In fact, the contents are almost totally secret, and the product itself is exempt from virtually all health regulation.
We provide a government subsidy for this product, and we know that it is at least contributory or perhaps causal in the deaths of 350,000 Americans a year. It would seem that if you looked at the spectrum of products sold in America, it stands out as an extraordinary exception to your mandate under the FDA and our concern as a government.
The product, of course, is tobacco and tobacco products. There have been tests over the years in court as to whether or not tobacco is included in the Food, Drug and Cosmetics Act, and the courts have generally concluded it is not. In fact, I think they have concluded unanimously that it is not an ingested food, nor is it a drug taken for an illness or to change some type of body structure.
I would like to ask you from a different perspective whether you can give me any medical or scientific basis for this exception that tobacco not be included as a product regulated by your agency.
Dr. YOUNG. I will ask Tom Scarlett to comment from a legal standpoint, but I suspect that from what you have said, that is not

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the direction you are coming from. Is that correct, not the legal aspect?

Mr. DURBIN. I think the legal interpretation is fairly clear that tobacco is not included in your legislative mandate. But I am asking from a medical or scientific viewpoint with your public health concern whether or not you can see any basis for this exception.

Dr. YOUNG. Dr. Koop and all of the Surgeon Generals that preceded him in recent years have focused on cigarette smoking as one of the major areas for concern. He and others before him have advocated a smoke free environment by the year 2000.

In my own experience as a pathologist, I have had the opportunity of dealing with and autopsying a number of people with lung cancer. There is no question that there have been certain diseases medically that have been implicated, whether directly or indirectly, with the consumption of tobacco. I don't think anyone will dispute that as a consensus. I think some will dispute that in different quarters. There is always dissent one way or another on the cutting edge of science.

The question comes in then how to focus on areas that do not seem to be within a mandate of a particular law. The chairman and I were talking about that earlier in regard to defining what a level of risk is when we were talking about the de minimis policy, how you handle that.

I had to deal with that—parenthetically, but it is directly related—when we were looking at a compound that I first dealt with when I came into the agency, acrylonitrile. Mr. Scarlett said this is under the food safety provision, not the Delaney Clause. It can be approved. There is a one in a million upward bound risk of an additional cancer.

A few months later, I looked at some of the colors. The upward bound risk was one in 19 billion, and they said that should be banned. I was thunderstruck. How could you ban one with a low risk and approve one with a little bit higher one.

I began to learn then that the law puts things in different packages. I said in attacking the de minimis approach that as a physician, it gives me no comfort to find someone dying under one provision appropriately or dying the same way under a different provision inappropriately. If you are dead, you are dead.

That comes back to the heart of your question of how do you deal with a very complicated issue.

From a medical standpoint, we have taken the substitution in the drug that we approved, Nicorette, as appropriate because there you could determine how this could substitute, and then see a person weaned if that person wanted to. However, my concern would be that it doesn't look like it is possible to regulate it under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health.

Mr. DURBIN. I would agree with the conclusion that it is not covered by the act. I would say that I have difficulty with that, though. I think the act was carefully crafted so that we could still have questions from my colleague from Hawaii about your investigation of alcohol and the additives to alcoholic beverages.

Dr. YOUNG. Yes.

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Mr. DURBIN. We know that that is used almost primarily for recreational uses and the like. We enjoy alcoholic beverages in this country. It is not a food per se, a nutrition source, although I am sure there is some nutrient value to a glass of beer and perhaps other alcoholic beverages.

However, what I am driving at is this. It strikes me that if on the one hand the drug, nicorette, or the drug, nicotine, is regulated by FDA, we know for a fact that nicotine is contained in virtually every tobacco product. We also know that because of your analysis of this nicorette or nicotine, you came to the conclusion that there should be some regulations perhaps as it relates to the sale or prescription of that drug.

Dr. YOUNG. Yes. That was really used to treat a nicotine withdrawal.

Mr. DURBIN. So, as you look at the tobacco product just on this aspect—and there is one other aspect I would like to address—we are dealing with a drug that is administered in an extraordinary way with little or no regulation. There are no prohibitions—I am sure there are some on the local and State basis, but none on a Federal basis that I am aware of—on the sale of tobacco products.

In this situation, virtually anyone of any age could come into possession of this drug and ingest it, but having done it by cigarette rather than by drug form, nicorette, they totally escape any Federal regulation. There seems to be some basic inconsistency here.

If our public goal is the public health of America, then the form of the drug as it is administered should be secondary to the goal, as I understand it. Perhaps I am taking you further than you are prepared to go today.

Dr. YOUNG. Tom, could you comment on that? In part, it is a legal question as to whether it is included under the act. Could you give us some history on that?

Mr. SCARLETT. Well, I don't want to belabor a point that Mr. Durbin has already acknowledged, namely, that the act draws lines and we have to respect them. I guess the one reaction that I was having to what you were saying was that what is fairly important in FDA law is whether a product has a therapeutic purpose, at least if you are talking about something that might be a drug.

Nicorette is intended to, in effect, treat cigarette addiction. Cigarettes themselves are not used for a therapeutic purpose as that concept is ordinarily understood. The opposite argument has been made and, I am sure, will be made over the years.

The other reaction I was having was that based on an experience that the CPSC had when it once undertook to ban bullets, a likely reaction that Congress might have if FDA attempted to regulate cigarettes would be to amend the FDA's law so that it could not.

Mr. DURBIN. I would agree that if you embarked on that course, you would definitely want some legislative support and, at this moment, it is not forthcoming. But I am attempting to explore that subject to determine whether or not it should be.

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The other area beyond the addictive quality of nicotine and tobacco is one that may be even more pernicious, and that is the question of tobacco additives. As I understand it, there is virtually no disclosure, certainly not to FDA, of additives in tobacco, whether they be pesticides, poisons, carcinogenic, or the like. So, in fact, there may be a product being sold on the market in America which could pose great health risk.

There are now cases pending involving liability of tobacco companies. I will not address any one specifically, because I think that would be uncalled for. But there have been disclosures in those trials that, in fact, sometimes there have been extraordinarily high pesticide residues on tobacco that has been sold to the American public.

You and I have talked for over a year now on pesticide levels on tomatoes coming in from Mexico and the efforts that we have made and the millions of dollars spent to protect the American consumers from any bad health effects. I think these efforts are well documented. Yet, in this instance, a chemical additive is going virtually unnoticed with no requirement for disclosure.

So, beyond the drug aspect of nicotine itself, what would you say to the concern over these chemical additives that are in tobacco products?

Dr. YOUNG. As far as I know, the regulation would be under the Bureau of Alcohol, Tobacco, and Firearms in regard to anything that would be there. To the best of my knowledge, one is not required to disclose any of the additives.

I think it is fair to say that regardless—I am now talking of the harmful chemical additive—if it were unchanged in consumption, it would be according to the principles that we have used in cancer evaluation—I will just stick with that field—that if it were not destroyed or modified by the smoke and heat, once you look at one route of entry, whether it be respiratory, skin, or GI, we have to assume that the residue is similar by any route.

I would be happy to go to my colleagues in BATF and see what I can learn about the ingredients. It is not an area that I am familiar with.

Mr. DURBIN. I know you don't need to broaden your already broad mandate, but if you would make some inquiry there, I would appreciate it.

Dr. YOUNG. I would be happy to, and I will provide that for you.

[The information follows:]

REGULATION OF ADDITIVES IN CIGARETTES

FDA staff have contacted the Bureau of Alcohol, Tobacco and Firearms (BATF) and has confirmed that BATF does not test cigarettes for pesticides or other chemical contaminants. It should be noted that The Federal Trade Commission has specific responsibilities regarding the labeling and advertising of tobacco products, but as far as we know they are not concerned with additives in cigarettes.

Mr. DURBIN. One last question on this particular subject. The chairman referred earlier to the Delaney Clause. We are familiar with its requirement, that the FDA remove any additives which could induce cancer in man or animal. We also know that unfortu-

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nately, we have about 80,000 lung cancers a year in the United States from smoking.

At the present moment, the way the Delaney Clause is constructed as an adjunct to the Food, Drug, and Cosmetic Act, you are powerless to address the carcinogenic aspects of smoking or tobacco.

Dr. YOUNG. That is correct. That would be viewed as being outside the scope of the Food, Drug, and Cosmetic Act as it is constructed today, and it would be a lacuna in regard to public health. I think that is why you see Surgeon General Koop and other Surgeon Generals going out and focusing at it with health education. That seems to be the way that is available to the public health service at this time.

Mr. DURBIN. Well, it is certainly beyond de minimis. When you think of the efforts that were made with a product like saccharine, for example, to alert the public of its potential carcinogenic qualities when consumed in quantity, it shows that we have really left a gap when it comes to public health as it relates to tobacco and smoking.

Dr. YOUNG. Yes. There is a warning, as you know, on the package, but that is the limit at this point.

Mr. DURBIN. Yes, and the warning is being used as a defense in many of these law suits on the basis that the smoker is assuming the risk. There is another aspect, of course, to selling an addictive product where perhaps a conscious and free decision is not being made each time as to the consumption of the product. But the courts will have to decide that.

I thank you for your comments, I am sure we are going to explore this a little further perhaps in the authorizing committee.

Dr. YOUNG. It is a tough issue, a very difficult issue.

PESTICIDES ON IMPORTED FOODS

Mr. DURBIN. Let me switch to an area that may be more familiar turf for us. I am very happy with the response which your agency has given me on the inspection for pesticides on imported food products. For those who are not familiar with it, several members of the staff joined me in a tour of several of your facilities. I was impressed with the people, the equipment, and the attitude of your employees. I think they do an extraordinary job.

Dr. YOUNG. They do an excellent job.

Mr. DURBIN. They do.

Dr. YOUNG. We are blessed with having outstanding people in the rank and file.

Mr. DURBIN. And they are behind the scenes, and I don't think most people appreciate that.

I had suggested that you might consider a procedural change when it came to the inspection of imported food products.

Presently under surveillance—and you can correct me if some of these facts have eluded me after a few months—you are taking samples of imported fruits and vegetables. After those samples are analyzed, if you find anything that is untoward or suspicious, you can put a producer on what is known as compliance status whereby they will be regularly inspected as they send in these products.

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